K090641

# 510(K) SUMMARY

OCT 23 2009

## 5.1 SPONSOR

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|---|---|
| Name: | Progentix Orthobiology BV |
| Address: | Professor Bronkhorstlaan 10, Building 48<br>3723 MB, Bilthoven, The Netherlands |
| Established Registration Nr: | n/a |
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## 5.2 U.S REPRESENTATIVE

| | |
|---|---|
| Name: | Columbia Pharma Consulting Services Inc. |
| Address: | 490 NW Datewood Drive<br>Suite 400<br>Issaquah WA 98027 USA |
| Established Registration Nr: | n/a |
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## 5.3 DEVICE NAME

Proprietary name: CuriOs™
Common/Usual name: Bone void filler
Classification name: Bone void fillers for orthopedics have not been classified (Product Code MQV) (unclassified)

## 5.4 PREDICATE DEVICES

Proprietary name: Vitoss™ Scaffold (OrthoVita), K994337
Proprietary name: OsSatura™ BCP (IsoTis), K030131

## 5.5 DEVICE DESCRIPTION

CuriOs™ is a micro-structured calcium phosphate resorbable bone void filler for the repair of bony defects. The product comprises of a beta-tricalcium phosphate and hydroxyapatite. The product is provided sterile.

## 5.6 INTENDED USE

CuriOs is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. CuriOs is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. CuriOs is intended to be packed

into bony voids or gaps of the skeletal system as a bone void filler (i.e., posterolateral spine and pelvis) and as an autologous bone graft extender in the posterolateral spine. CuriOs should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. In load bearing situations, CuriOs is to be used in conjunction with internal or external fixation devices

## 5.7 TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

CuriOs™ is a synthetic, osteoconductive and resorbable bone void filler comprised of beta–tricalcium phosphate and hydroxyapatite. CuriOs™ has a trabecular structure that resembles the structure of human cancellous bone. The osteoconductive nature of CuriOs™ guides the regeneration of new bone following its implantation into the defect site. The ceramic implant resorbs and is replaced by bone and soft tissue during the natural process of bone remodeling.

The safety and effectiveness of the CuriOs™ bone void filler is adequately supported by the substantial equivalence information, safety and performance data provided in this Premarket Notification. CuriOs™ and the predicate devices are essentially similar in design, materials of construction and function. They all have the same intended use. CuriOs™ has been compared in physico-chemical and pre-clinical testing with the predicate devices, which confirmed the similar composition, resorption profile, safety, biocompatibility and effectiveness. The safety and biocompatibility testing performed for calcium phosphates in general, and the long history of safe clinical use for these materials further support the safe use of CuriOs™. CuriOs™ meets the applicable requirements of the FDA guidance documents on bone void fillers.

## 5.8 PERFORMANCE DATA

The CuriOs™ is tested to conform to applicable requirements of the recognized standards. The devices to which the CuriOs™ claims substantial equivalence are Vitoss™ Scaffold (OrthoVita) and OsSatura™ BCP (IsoTis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Progentix Orthobiology BV
% Ms. Yvonne Bovell
Professor Bronkhorstlaan 10, Building 48
Bilthoven
Netherlands 3723 MB

OCT 2 3 2009

Re: K090641
Trade/Device Name: CuriOs
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 24, 2009
Received: August 25, 2009

Dear Ms. Bovell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4. INDICATIONS FOR USE STATEMENT

## Indications For Use

**510(k) Number (if Known):** K090641

**Device Name:** CuriOs™

**Indications for Use:** CuriOs is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. CuriOs is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. CuriOs is intended to be packed into bony voids or gaps of the skeletal system as a bone void filler (i.e., posterolateral spine and pelvis) and as an autologous bone graft extender in the posterolateral spine. CuriOs should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. In load bearing situations, CuriOs is to be used in conjunction with internal or external fixation devices.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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